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09/667,932	09/22/2000	Thomas Kissel	514429-3640	9309

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EXAMINER	
NGUYEN, DAVE TRONG	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/667,932	Applicant(s) KISSEL ET AL.	
	Examiner Dave Nguyen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,20-25 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

Applicant's election with traverse of Group I (claims 1-14, 20, 21-25, drawn to a vector comprising a LMW PEI and a DNA, and methods of making the vector), species of a non viral construct, species of a DNA encoding a fusion protein comprising an enzyme fused to a cell specific ligand, and species of the ratio by weight of LMW PEI to nucleic acid which is 3: 1 or more, in the response filed January 24, 2002 is acknowledged.

The traversal is on the ground(s) that:

- The claims of Groups I to IV are all related and are directed to the same inventive concept;
- The claims in Groups I to IV may be searched and examined together without serious burden as they are all related to the vectors comprising LMW PEI and a DNA claimed in Group 1, particularly since searching the claims of Group I (PEI and DNA) would necessarily overlap and include a search of the individual pharmaceutical compositions and gene therapy methods using the vectors in Groups II and III;
- The inventions of Groups I to III are related and the requirements of the two-part test are not fulfilled, particularly since not all proteins and/or antibodies that can be produced *in vitro* can be produced by *in vivo* methods, and since the processes cited in Groups II, III, and IV all require the use of the vectors of Group I, and thus, cannot be used to make other and materially different products;
- The methods of preparing and using the LMW are novel and nonobvious, the vectors that incorporate LMW PEI are als0o novel and that the methods of using LMW PEI compositions and vectors containing LMW PEI should be examined together in one application;
- Duplicate searching of the various Groups in separate divisional applications would be quite inefficient to the operation of the US PTO; and
- In view of GATT and the unreasonable cost of filing and prosecuting divisional applications, the restriction would constitute an undue burden to Applicants, and

would not benefit the public.

Applicant's traversal has been considered fully by the examiner and is found persuasive in-part as follows:

The restriction has been modified as follows:

The following claims have been rejoined to the claimed invention of Group I because the search for prior art of the claimed invention of group I would encompass the search for prior art of the subject matter being sought in the rejoined claims: 28-29 drawn to the use of LMW PEI/nucleic acid complexes for *in vivo* gene therapy, wherein claim 27 is treated as a linking claim which embraces *in vivo* nucleic acid applications; Claim 30 which recites a method of making a pharmaceutical containing a DNA and a LMW PEI; Claims 31, drawn to a DNA pharmaceutical comprising a LMW PEI and a DNA. In addition, claim 27 has been rejoined to the claimed invention of Group IV.

Applicant' assertions as to the non-distinction among *in vivo* and/or *ex vivo* gene therapy methods, processes of preparing a LMW PEI and pharmaceutical products produced by the processes, and the claimed invention of Group I (claims drawn to LMW PEI/DNA complexes, transfected cells containing the LMW PEI/DNA complexes, and methods of preparing the transfected cells and the LMW PEI/DNA complexes) are not found persuasive for the reasons of record and the reasons as follows:

Inventions I, III and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the LMW PEI/DNA complexes cited in Invention I is not limited for use in the processes cited in invention III and can be use in an *in vivo* diagnostic assay wherein a LMW PEI/DNA complex is employed to deliver a reporter gene or an imaging agent to a target tissue *in vivo,* or can be use for producing antibodies *in vivo* and/or *in vitro.* In addition, a literature search for the gene therapy methods and/or method steps of Invention I and/or

Invention III would not necessarily include methods of making a LMW PEI as recited in Invention IV. Furthermore, claims drawn to LMW PEI or its use do not require DNA for its utility and the DNA complexes and/or method using the DNA complexes of Invention I and III have multiple uses themselves, and thus, a search and/or examination of just PEI itself or its unspecified use as claimed in claim 27 do not necessarily embrace that of Invention I or Invention III. For these searches different search terms and different references would be identified, which would require separate consideration, and thus, a search of the invention of Invention I in addition to the inventions of Groups II, III, and IV would be unduly burdensome to the examiner. Thus, the requirement of the either one of the two-part test has been met by the examiner, and furthermore, it would be unduly burdensome for the examiner to search and consider patentability of the claimed inventions I, III, and IV altogether in one application. Applicant's assertion regarding the urn-obviousness of the claimed invention of Group I, the cost and inefficiency resulted from the maintained restriction, and the undue burden on applicants have been noted; however, applicant's comments are not found persuasive in view of the reasons set forth above. In addition and as evidenced by MPEP guidelines, only one invention per application is examined for patentablity.

Therefore, the requirement is still deemed proper and is therefore made FINAL. Claims 15-19, 26, 27, 32, 33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Elected claims 1-14, 20-25, 28-31, to which the following grounds of rejection are applicable, are pending.

The information disclosure statement filed on September 28, 1998 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each publication listed that is not in the English language. The Vollmert (identified as AJ in the IDS filed 9/12/00), DE 196 49645.4 (identified as AD filed 9/12/00), and EP 0,790,312 A2 (identified as AC in the IDS filed 9/12/00) have been placed in the application file, but the information referred to therein has not been considered. In addition, the Godbey *et al.* reference (identified as AV in the IDS filed 9/12/00) does not have the publication year, and thus, while the reference has been lined through in the IDS for non-compliance.

Acknowledgement is made of applicant's claim for foreign priority based on the German application filed 9/20/1997. It is noted, however, that applicant has not filed a certified copy of the application as required by 35 USC 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application and the pending claims encompass methods of making a pharmaceutical comprising a LMW PEI and a DNA; and pharmaceutical products comprising a LMW PEI and a DNA. The specification indicates on page 3 that "pharmaceutical" products are employed to achieve the prophylaxis or therapy of any disease and/or all diseases. The specification provides

sufficient guidance and/or evidence showing *in vitro* transfection of a target cell with a DNA composition comprising a LMW PEI and a plasmid DNA encoding a reporter gene product.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification teaches on pages 2 and 3 that any DNA when employed with a carrier composed of a low molecular weight polyethylenimine (LMW PEI) as a pharmaceutical, prophylaxis or therapy of any and/or all diseases will be achieved. However, the state of the art exemplified by Verma *et al.* (Nature, Vol. 389, 18, September 1997) states that "the Achilles heel of gene therapy is gene delivery", that "thus far, the problem has been an inability to deliver genes efficiently and to obtain sustained expression", that gene delivery methods using non-viral vectors "suffer from poor efficiency of delivery and transient expression of the gene", and that "although there are reagents that increase the efficiency of delivery, transient expression of the transgene is a conceptual hurdle that needs to be addresses" (page 239, column 3, first paragraph). In addition, Godbey *et al.* (J. Biomedical Materials Research , 45, 3, pp. 268-275, 1999) provide evidences showing that hurdles including the molecular weight and/or size of carriers including PEI polymers need to be addresses before attempting to use the carriers for gene therapy (page 275, column 1, last paragraph). Furthermore, Verma *et al.* indicate that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2). However, other than *in vitro* expression of a luciferase gene product using a LMW PEI/plasmid complex as a delivery system, the specification does not provide sufficient guidance and/or factual evidence demonstrating a reasonable correlation between the disclosure including its exemplified examples and the subject

matter being sought in the claims. Thus, it is not apparent how one skilled in the art determines, without undue experimentation, which of the disclosed DNA complexes generates a therapeutic effect in any and/or all gene therapy methods, nor is it apparent as to how one skilled in the art reasonably extrapolates from the *in vitro* expression of a reporter gene product as exemplified by the specification to any and/or all pharmaceutical products as recited in the presently pending claims, particularly given the unpredictability of gene therapy and/or the doubts expressed in the art of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-14, 20-25, 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, the "nucleic acid construct" lacks an antecedent basis.

Claim 9 is indefinite because it is not apparent as to how a "effector" gene which is a DNA sequence of nucleotide residues is expressed together with a cell specific ligand which a sequence of amino acid residues as a fusion protein. It is not apparent as to what structural context in which the effector gene and the ligand are expressed together.

In claim 11, "the cell-specific ligand" lacks an antecedent basis.

In claim 12, "the target cell" lacks an antecedent basis.

Claim 21 is indefinite in the recitation of "appropriate" because it is not apparent as to what exactly the metes and bounds of the degrees and/or amounts is meant for the "appropriate" as intended by applicants.

In claim 24, the term "this cell" is indefinite because it is not apparent as to what are exactly cell(s) that "this cell" refers to.

In addition, all dependent claims 1-14, 20-25, 28-31 which recite "A vector as claimed..." or "a vector according to" are indefinite because it is not apparent as which of the vectors from the base

claims is intended for "a vector"? A change from "A vector as claimed", "a vector according to"" to "The vector as claimed..." would obviate the rejection.

Claims 22-23, 28-29 provide the use of the vector of claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method, process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 22-23, 28-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki,* 153 USQP 678 (Bd.App. 1967) and *Clinical Products, Ltd. V. Brenner,* 255 F. Supp. 131, 149 USPQ 475 (D.D.C., 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

In view of compact prosecution, claims 22, 23 are treated as embracing a gene delivery process comprising delivering the vector of claim 1 into a cell. In addition, claims 28, 29, 30 are readable on a composition comprising the vector of claim 1 and a pharmaceutically acceptable carrier.

Claims 1-3, 5-8, 10-13, 21-25, 28-31, are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Behr *et al.* (US Pat No. 6,013,240)

The claims encompass a LMW PEI/DNA complex, gene delivery methods using the LMW PEI/DNA complex, host cells comprising the LMW PEI/DNA complex, wherein the LMW PEI has a molecular weight of less than 50, 000 dalton (Da) and/or 1,000 Da.

Behr *et al.* teach a PEI/DNA complex wherein the average molecular weight of the PEI polymer is 100 Da or 1000 Da (claim 1, column 2, lines 30 and 31). Behr *et al.* teach that the DNA encodes cytokines including interleukins, interferons, tumor neucrosis factor (TNF), enzyme, thymidine kinase, and tumor suppressor proteins (column 3). Column 4 of Behr *et al.* also discloses that the DNA encodes a fusion protein comprising a signal sequence or a ligand that includes a nuclear localization sequence. Column 5 of Behr *et al.* further discloses that a targeting ligand is complexed to the PEI polymer. Column 6 of Behr *et al.* discloses *in vitro* and/or *in vivo* gene transfer method using the PEI/DNA complex for delivering the DNA to a target host cell. Behr *et al.* also teach that any and/or host cells including fibroblasts, liver cells, carcinomas, kidney cells and neuron can be targeted for delivery using the PEI/DNA complex (column 6, second paragraph). Regarding the ratio of PEI to DNA, Behr *et al.* teach that the ratio varies from 6 to 45 equivalents (column 9, lines 41-46). Behr *et al.* also teach on column 6 pharmaceutically acceptable carriers that are employed together with the PEI/DNA complexes.

To the extent that the claims encompass PEI polymers with any molecular weight of from 500 to 30,000 Da or from 1,000 to 5,000 Da, wherein the molecular weight is not at about 2000 Da, Behr *et al.* teach that the molecular weights of PEI polymers are between 100 and 1,000,000,0 Da, and/or are

between 1,000 and 5,000,000 Da (column 2, lines 30 and 31). Thus, it would have been obvious matter of design choice to make any PEI with molecular weights other than the 2,000 MW that fall between the range disclosed in Behr *et al.* because such a modification would have involved a mere change in the molecular weight of PEI, particularly since a change in molecular weight as claimed is recognized in Behr *et al.* as being within the level of one of ordinary skill in the art.

Absent evidence to the contrary, the PEI/DNA complex, host cells comprising the complex, compositions comprising the complex, and gene transfer methods using the complex of Behr *et al.* have all of the properties cited in the claims.

Claims 1-3, 5-8, 11-13, 21-25, 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as being unpatentable German *et al.* (US Pat No. 5,830,730).

The claims encompass a LMW PEI/DNA complex, gene delivery methods using the LMW PEI/DNA complex, host cells comprising the LMW PEI/DNA complex, wherein the LMW PEI has a molecular weight of less than 50, 000 dalton (Da) and/or 3,000 Da.

German *et al.* teach a plasmid DNA/adenovirus/PEI complex as a gene delivery composition, wherein PEI has a molecular weight of 3,000 Da (column 3). In addition, German *et al.* teach that the DNA encodes a bacterial enzyme or an SV40 large T antigen on column 5. Regarding the ratio cited in claim 13, German *et al.* teach that the preferred ratio of PEI to DNA is about 4:1 (column 4, lines 39 and 40). German *et al.* also teach that the OPTI-MEM-1-media is employed as a pharmaceutically acceptable carrier on column 4. Regarding the host cells employed for the delivery of the plasmid DNA, German *et al.* teach that the plasmid DNA are delivered to mouse islet cells, tumor cells and primary cultured cells (column 5).

To the extent that the claims encompass PEI polymers with any molecular weight of from 500 to 30,000 Da or from 1,000 to 5,000 Da, wherein the molecular weight is not at about 2000 Da, German *et al.* teach that it is routine in the art to make cationic polymers having groups comprising primary amines and secondary or tertiary amines, including the PEI polymers having the molecular weight as low as 3000 MW (column 3, lines 31-48). Thus, it would have been obvious matter of design

choice to make any PEI with molecular weights other than the 2,000 MW which are from 500 to 30,000 Da or from 1,000 to 5,000 because such a modification would have involved a mere change in the molecular weight of PEI, particularly since a change in molecular weight as claimed is recognized in German *et al.* as being within the level of one of ordinary skill in the art.

Absent evidence to the contrary, the PEI/DNA complex, host cells comprising the complex, compositions comprising the complex, and gene transfer methods using the complex of Behr *et al.* have all of the properties cited in the claims.

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Behr *et al.* (US Pat No. 6,013,240) or German *et al.* (US Pat No. 5,830,730) taken with either Thorpe *et al.* (US Pat No. 6,036,955) taken with Friden *et al.* (US Pat No. 5,977,307).

The rejection of the base claim 1 as being anticipated by either Behr *et al.* or German *et al.* is applied here as indicated above. Either Behr *et al.* or German *et al.* do not teach explicitly that the DNA encodes a fusion protein comprising a cell specific ligand and an effector protein.

However, at the time the invention was made, either Thorpe *et al.* (abstract, and column 53) or Friden *et al.* (column 3 bridging column 4) teach that fusion protein encoded DNA comprising a cell-specific ligand encoded gene operably linked to an effector gene are known in the art and have been employed to deliver the DNA to a target cell.

It would have been obvious for one of ordinary skill in the art to have employed the PEI delivery compositions of either Behr *et al.* or German *et al.* to deliver the fusion encoded DNA of either Thorpe *et al.* or Friden *et al.* to a cell of interest. One of ordinary skill in the art would have been motivated to have employed the PEI delivery compositions of either Behr *et al.* or German *et al.* to deliver any DNA including the encoded DNA of either Thorpe *et al.* or Friden *et al.* to a target cell because either Behr *et al.* or German *et al.* teach that PEI contained delivery compositions are effective for enhancing the delivery of any and/or all DNA(s) to a target cell.

Thus, the claimed invention as a whole was *prima facie* obvious, and absent evidence to the contrary, the DNA delivery compositions of the combined cited references have all of the properties cited in the claims.

Claim 4 is free of the art of record because the prior art of record does not teach or suggest that PEI having a molecular weight of 2,000 Da is more effective than other known PEI polymers for delivering a DNA of interest to a target cell.

No claims are allowed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER